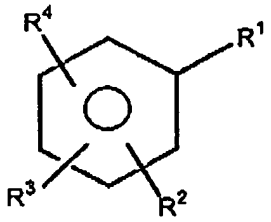
al. (U.S. 5,895,643) or Hoppe et al. in view of D'Augustine et al.

Claim 1 is directed to an exoprotein inhibitor for inhibiting the production of exoproteins from Gram positive bacteria in and around a vagina. The exoprotein inhibitor comprises a non-absorbent substrate for insertion into the vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. The non-absorbent substrate has deposited thereon an effective amount of a first active ingredient having the general formula:

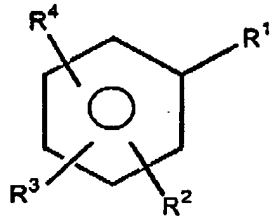


wherein R^1 is $-OR^6OH$; R^6 is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^2, R^3, and R^4 are independently selected from the group consisting of H, OH, COOH, and $-C(O)R^9$; R^9 is hydrogen or a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety, wherein the first active ingredient is effective in inhibiting the production of exoprotein from Gram positive bacteria.

D' Augustine et al. disclose devices, methods, and compositions for treating vaginal fungal, bacterial, viral, and parasitic infections by intravaginal or transvaginal administration of therapeutic and/or palliative antifungal,

antibacterial, antiviral or parasiticidal drugs to the vagina or to the uterus. Specifically, a device such as a tampon, tampon-like device, vaginal ring, pessary, cervical cup, vaginal sponge, intravaginal tablet, or intravaginal suppository, delivers the drug, which can be in the form of a paste, cream, ointment, microcapsule, solution, powder, or gel having a sufficient thickness to maintain prolonged vaginal epithelium and mucosa contact. In one embodiment, the drug can be incorporated into a cream, lotion, foam, paste, ointment, or gel which can be applied to the vagina using an applicator.[1]

As noted by the Office, D' Augustine et al. fail to teach the first active ingredient as required in claim 1, which has the general formula:



wherein R^1 is $-OR^6OH$; R^6 is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^2, R^3, and R^4 are independently selected from the group consisting of H, OH, COOH, and $-C(O)R^9$; R^9 is hydrogen or a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety, wherein the first active ingredient is effective in inhibiting the production of exoprotein from Gram positive bacteria. In an attempt to find each and every element

[1] D' Augustine et al. at column 18, lines 24-26.

of claim 1 as required by the M.P.E.P. for a determination of *prima facie* obviousness, the Office cites the Hoppe et al. reference for combination with D' Augustine et al.

Hoppe et al. disclose a deodorizing or antibacterial composition comprising: at least one 3,7,11-trimethyl-2,6,10-dodecatrien-1-ol, at least one phenyl hydroxyalkyl ether having one, two, or three carbon atoms in the alkyl radical (i.e., 2-phenoxyethanol), at least one glycerol monoester or a short-chain or medium-chain fatty acid, and optionally glycerol monolaurate. The deodorizing or antibacterial composition is particularly useful in cosmetic or topical formulations for suppressing unpleasant body odor that forms as a result of the formation of intensely smelling decomposition by-products from certain skin bacteria. No where do Hoppe et al. suggest or disclose the use of any deodorizing or antibacterial composition inside of a vagina.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art references must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and (3) there must be some reasonable expectation of success. The Office has failed to meet its burden under (2) above, as there is no motivation or suggestion to combine the D' Augustine et al. and Hoppe et al. references to arrive at Applicants' claim 1.

As noted in M.P.E.P. §2142, in establishing obviousness, the Office must show references that teach all of the claimed

limitations along with some motivation or suggestion, either in the references themselves or in knowledge generally available to one skilled in the art, to combine the references and arrive at the claimed subject matter.[2] The mere fact that the references can be combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. In re Mill, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the D' Augustine et al. and Hoppe et al. references would not have been made.[3]

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[2]As further set forth in M.P.E.P. §2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the reference itself, or in the knowledge generally available to one of ordinary skill in the art.

[3]M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

The Office asserts that Hoppe et al. provide sufficient motivation to use the safe, non-toxic, anti-bacterial and odor preventing composition of Hoppe et al. in the vaginal device of D' Augustine[4] due to the desire to provide a highly effective antibacterial and treatment for reducing bacterial infections in the vaginal area and also reduce the odor, and because Hoppe et al. state that a completely satisfactory deodorizing composition is linked with the characteristic of excellent skin and mucosa tolerance. With all due respect, Applicants submit that this is not a convincing line of reasoning as to why the combination of these references would have been obvious. Specifically, why would one skilled in the art pick Hoppe et al.'s composition over all of the other non-toxic, anti-bacterial compositions in the art?

D' Augustine et al. simply teach compositions that can be used as anti-bacterials to treat bacterial infections of the vagina and devices for delivering the compositions; and even provide several commercially acceptable anti-bacterial compositions. The D' Augustine et al. reference fails to provide a reason why one skilled in the art would choose another

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[4] The Office asserts that the D'Augustine et al. reference is directed to a device in the form of a non-absorbent tampon or tampon-like device. Office Action dated June 16, 2005 at pages 3 and 4. Applicants note, however, that D'Augustine et al. never disclose a *non-absorbent* tampon. Specifically, at column 3, lines 5-6 of the D' Augustine et al. reference, the reference states that the device can be an *absorbent* intravaginal tampon or tampon-like device. As such, the tampon or tampon-like device does not meet the limitation of a non-absorbent substrate as required in claim 1 of Applicants' invention.

anti-bacterial over those listed in the D' Augustine et al. reference or disclosed elsewhere in the art. The Hoppe et al. reference is directed to anti-bacterial compositions suitable for suppressing unpleasant body odor. While the anti-bacterial composition of Hoppe et al. can be used for suppressing body odor in the genital region, why would one skilled in the art look to the Hoppe et al. anti-bacterial, odor preventing composition over any other anti-bacterial compositions for use in the intravaginal devices of D' Augustine et al.? No where in Hoppe et al. is it disclosed to use the anti-bacterial, odor preventing composition for the treatment of vaginal fungal, bacterial, viral, and parasitic infections.

Moreover, a close reading of the Hoppe et al. reference actually teaches away from the exoprotein inhibitor of claim 1. Specifically, at column 1, lines 46-47, Hoppe et al. teach that phenyl hydroxyalkyl ethers such as 2-phenoxyethanol are chiefly directed against Gram negative bacteria. As noted above, instant claim 1 is directed to inhibiting the exoproteins from Gram positive bacteria. As such, one skilled in the art would not, and could not, be motivated to use the anti-bacterial, odor preventing composition directed against Gram negative bacteria of Hoppe et al. in the intravaginal devices of D' Augustine et al. to arrive at each and every limitation of Applicants' claim 1.

Additionally, and importantly, one skilled in the art recognizes that the bacteria flora and bacteria equilibrium that exists inside of the vagina of a woman is highly complex and substantially different than flora on the skin. As such, one skilled in the art would not be motivated to use an odor

preventing composition directed solely at topical use inside of a vagina because of the enormous potential health risks.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when combining the D' Augustine et al. reference with the Hoppe et al. reference. Notably, it would be clear to one skilled in the art reading D' Augustine et al. that an anti-bacterial composition be used to treat bacterial vaginal infections. There are, however, a myriad of anti-bacterial compositions, many of which are used to treat vaginal infections. What is important is that there is no motivation or suggestion to use the composition of Hoppe et al., which is solely directed at topical use and not intravaginally, over any of the other enormous number of anti-bacterial compositions described in the art, which are suitable for use in a vagina.[5]

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[5] It is noted that the Office states that Hoppe et al. teach phenyl hydroxyalkyl ethers such as 2-phenoxyethanol as well-known **antibacterial** agents. It is worth noting at this time that the first active ingredient used in the exoprotein inhibitor of claim 1 of the present invention is not acting as an antibacterial agent as apparently understood by the Office. As mentioned in Applicants' specification, the first active ingredient acts to **inhibit the production of exoproteins** from Gram positive bacteria, but does not seek to kill the bacteria as the killing of bacteria is non-selective and the "good" bacteria needed to maintain a healthy vagina would also be killed. Thus, the non-selective killing of bacteria could actually be very harmful to the vagina and could cause serious health problems. This is significant. The first active ingredient as claimed in claim 1 of the present invention actually seeks not to act as an antibacterial agent as claimed by the Office, but seeks to only prevent the production of potentially harmful by-products of bacteria, while allowing the bacteria to live. It is also noted that none of the cited references suggest or disclose that a composition having the

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As there is no motivation or suggestion to combine the D'Augustine et al. and Hoppe et al. references to arrive at each and every limitation of claim 1, claim 1 is patentable over D'Augustine et al. in view of Hoppe et al.

Claims 3-4, 6-11, and 14-25 depend directly or indirectly on claim 1. As such, claims 3-4, 6-11, and 14-25 are patentable for the same reasons as claim 1 set forth above, as well as for the additional elements they require.

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Letter To Patent And Trademark Office to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully Submitted,

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general formula of the first active ingredient of claim 1 can act in such a manner.